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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,763	08/19/2003	Francisco Veas	1721-67	3291

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EXAMINER	
HUMPHREY, LOUISE WANG ZHIYING	
ART UNIT	PAPER NUMBER
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/642,763	VEAS, FRANCISCO	
	Examiner	Art Unit	
	Louise Humphrey, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-38 and 40-49* is/are pending in the application.

4a) Of the above claim(s) *45,46,48 and 49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-38,40-44 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner of your application in the Patent and Trademark Office has been changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Louise Humphrey, Art Unit 1648.

It is noted that there were typographical errors in the statements of rejections under 35 U.S.C. §102(a) over DeVico *et al.* and Kwong *et al.* These two rejections are under 35 U.S.C. §102(b). See below.

This Office Action is in response to the amendment filed 23 October 2006. Claims 1-21 and 39 have been canceled. Claims 46-49 have been added. Amended claim 45 reads on a different invention comprising different pathogenic agents from the instantly examined viruses. New claims 45, 46, 48 and 49 read on different inventions employing a different first means of the composition. Therefore, claims 45, 46, 48, and 49 are withdrawn from further consideration.

Claims 22-38, 40-44, and 47 are under examination.

The objection to the title is **withdrawn** in view of the Applicant's amendment.

The objection to claim 41 is **withdrawn** in view of the Applicant's amendment.

The objection to the specification is **maintained**. The specification filed on 19 August 2003 contains unidentified nucleotide sequences on page 13 and 17-19. Even though the sequence on top of page 13 is identified by a Genbank accession number, it

is not in compliance with the sequence rules. Every sequence is to be appended with a SEQ ID NO with a paper listing of the sequences and an electronic copy.

The rejection of claims 22-24, 33, 35, 37-39, 44 and 45 under 35 U.S.C. §112, second paragraph, as being indefinite is **withdrawn** in view of the amendment.

The rejection of claim 24 under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement, is **withdrawn** in view of the amendment.

The rejections of claims 22 and 42 under 35 U.S.C. §101, as being inoperative and therefore lacking patentable utility, and under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification commensurate in scope are **maintained**. Applicant's argument has been fully considered and is not persuasive.

Applicant argues that the claims do not refer to vaccines while reading on immunogenic compositions. Examiner respectfully disagrees. An immunogenic composition can be used to recognize an infectious agent as well as to protect against the infection of a pathogen. Therefore, the specification does not reasonably provide enablement for an immunogenic composition that prevents pathogenic infection, as already indicated in the prior Office Action. Since the instant claims do not specify whether the immunogenic composition is for recognition or prevention of infection, the specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection of claims 22-24, 26-37 and 41 under 35 U.S.C. §102(b) as being anticipated by LaCasse *et al.* (15 January 1999) is **maintained and extended** to amended claim 44. Applicant's arguments have been fully considered but are not persuasive.

Applicant argues that there is no disclosure or suggestion of the control of the progression of the fusion to have different complexes depending on the fusion progress with therefore the possibility to raise different antibodies at each step of the fusion progress. Secondly, Applicant asserts that the invention relates to the use of a molecular system rather a cellular system, which cannot be exploited in humans.

The instant claims are product-by-process claims and are not limited to the manipulations of the recited steps, only the structure implied by the steps. See MPEP § 2113. The control of the progression of the fusion and conditions to perform the fixation is clearly taught in reference under the section References and Notes. Furthermore, LaCasse *et al.* never limits the process to only one immunogenic complex at one step of the fusion progress. It is unclear what Applicant means by "a molecular system" versus a "cellular system" as the vectors require host cells to express target receptor proteins. The immunogens taught by LaCasse *et al.* meet the structural limitations recited in the claims, thus, LaCasse *et al.* anticipates the instant invention.

The rejection of claims 22, 26, 29, 30, 36 and 37 under 35 U.S.C. §102(a) as being anticipated by Schønning *et al.* (1999) is **maintained** until Applicant files the English translation of the foreign priority document.

The rejection of claims 22, 31, 38, 39 and 41 under 35 U.S.C. §102(b) as being anticipated by DeVico *et al.* (1995) is **maintained**. Applicant's arguments have been fully considered but are not persuasive.

Applicant argues that the complexes of the presently claimed invention are formed by fusion in a molecular system. Applicant does not differentiate the difference between the "molecular system" and the prior art. Most importantly, Applicant does not present evidence showing structural difference between the immunogenic complex taught by DeVico *et al.* and the invention. See M.P.E.P. §2113.

The rejection of claims 22, 31, 38, 39 and 41 under 35 U.S.C. §102(b) as being anticipated by Kwong *et al.* (1998) is **maintained**. Applicant's arguments have been fully considered but are not persuasive.

Applicant argues that there is no teaching on the study and identification of complexes formed at determined intervals of the fusion. Similar to responses to the aforementioned rejections, Applicant is arguing about a feature of the process, but the invention is a product of immunogenic compositions. Absent evidence of structural difference in the prior art, the instant invention is anticipated by Kwong *et al.*

Applicant stated that each of the rejection under §103(a) is "traversed" based on the same reason used for the primary references used in the rejections under §102 above.

The rejection of claims 22, 25 and 41 under 35 U.S.C. §103 (a) as being obvious over DeVico *et al.* (1995) or Kwong *et al.* (1998) in view of Rigaud *et al.* (1995) **is maintained** for reasons of record.

The rejection of claims 22 and 40 under 35 U.S.C. §103 (a) as being obvious over LaCasse *et al.* (1999) in view of Rissio *et al.* (1998) **is maintained** for reasons of record.

The rejection of claims 22-24, 26-40, and 41 under 35 U.S.C. §103 (a) as being obvious over LaCasse *et al.* (1999) in view of Riley *et al.* (1998) **is maintained** for reasons of record.

New Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 24, 43, 44 and 47 are rejected under 35 U.S.C. §103(a) as being unpatentable over LaCasse *et al.* (1999) in view of Murphy *et al.* (1990).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the composition of LaCasse *et al.* by expressing the HIV envelope genes and human CD4 in a baculovirus expression vector as taught by Murphy *et al.* The skilled artisan would have been motivated to do so to optimize the expression of the immunogens. There would have been a reasonable expectation of

success, given that DNA constructs encoding CD4, gp120, gp160, and gp160 fragment cloned into the baculovirus expression vector pVL941 produced native HIV envelope proteins and recombinant human CD4 that interact with each other, as taught by Murphy *et al.* Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Jeffrey Parkin, Ph.D.
Primary Examiner
05 January 2007

1/5/07